

Remarks Regarding Rejections under 35 U.S.C. § 102

Claims 1 stands rejected as allegedly anticipated by U.S. Patent No. 6,120,500 issued to Bednarek et. al. (hereafter "Bednarek"). Applicants have amended Claim 1 to incorporate the limitations of claim 2, namely, "wherein said cross-sectional configuration of said active region includes a flattened outer peripheral wall."

The Examiner implicitly acknowledged that this limitation was not in Bednarek, and accordingly, it is respectfully submitted that the amended claim 1 is not anticipated by Bednarek. Applicants will address the obviousness rejection of claim 2 below. No new matter is introduced by this amendment and support for this amendment is found in original claim 2 .

Applicants respectfully request that the Section 102 rejection of claim 1 be withdrawn.

Remarks Regarding Rejections under 35 U.S.C. § 103

In order to “establish a prima facie case of obviousness, three basic criteria must be met.” MPEP § 7.06.02(j). First, there must be some motivation or suggestion to modify the reference or to make the proposed combination. Second, there must be a reasonable expectation of success. “The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant’s disclosure.” MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Third, the combined references must teach or suggest all claim limitations.

“There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Applicants respectfully submit that there is no proper motivation to combine the reference cited in Examiner’s Section 103 rejection. In fact, the second reference cited teaches away from Applicants’ invention.

§ 103 Rejections based on Bednarek and Cioanta

Claims 2 and 8 (and all claims depending therefrom)

Claims 2, 5-9, 11, 12, 14/12 and 15-18 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bednarek further in view of U.S. Patent Publication 2002/0082556 to Cioanta et. al. (hereafter "Cioanta"). Examiner asserts:

Bednarek et. al. teach all of the limitations of the claims except the cross-sectional configuration including a flattened outer peripheral wall and the dimensions of the aspect ratio as claimed. Cioanta et. al. disclose a catheter and teach that it is old and well known in the art to provide a catheter with a cross-sectional perimeter of various shapes as a mere design choice. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the [Bednarek] catheter such that its cross sectional perimeter includes a flattened outer peripheral, particularly in view of the teaching of Cioanta

(Office action at 3). Applicants respectfully disagree.

The nature of the problem addressed by Cioanta is completely different from Applicants' invention. Cioanta's title makes the difference clear – "Treatment Catheters with **Thermally Insulated Regions**."

Cioanta seeks to solve a particular problem associated with thermal ablation catheters, namely, losses of thermal energy along the tubular lengths that transport the energy to treatment regions. In Cioanta, "[c]ertain embodiments of the catheter cross-sectional profile or perimeter shapes shown in Figs. 3 and 4 include a plurality of partitions or segments forming a part of the *insulated shaft region* The plurality of segments are located **between the outer wall** and the circulating fluid lumens. The plurality of

segments can define discrete enclosed void spaces. Each of the **void spaces** also have perimeter shapes, typically oval, circular, or curvilinear, or polygonal such as in the shape of a triangle, square, rectangle, parallelogram, trapezoid, and the like.” (Paragraph 0077) (emphasis added).

The various cross-sectional perimeters referred to in Cioanta are directed to the **void spaces within the insulated shaft region of the catheter**. They are not directed to the outside cross-sectional perimeter of the catheter itself, all of which are circular (and none of which are flattened) throughout the insulated shaft region. More significantly, the design choices in Cioanta are all directed toward solving problems associated with the insulated shaft region of the catheter, not the treatment region of the catheter. Applicants’ invention provides various cross-sections around its outside perimeter (including a flattened outer peripheral) in the active (treatment) region of the catheter which improve the contact between the treatment region and the tissue being treated.

A closer look at some of the teachings of Cioanta reveals the fundamentally different nature of the problem that Cioanta is trying to solve:

More particularly, in one embodiment of the present invention, a treatment catheter can be configured ... The treatment catheter comprises a flexible elongated tubular body having a thin outer wall with an external surface and at least one fluid lumen axially extending therein. The tubular body comprises a region having increased thermal insulation relative to another region thereof. The increased thermal insulation region extends a longitudinal length along the tubular body. The increased thermal insulation region includes **a material configuration which provides sufficient thermal insulation** between the at least one fluid lumen and the external surface **to inhibit thermal ablation of non-targeted tissue....**

In certain embodiments, the present invention can also provide segments with spaces which are oriented and shaped to **reduce the amount of contact area** between the internal lumen and/or the outer wall and/or to provide **increased** lateral or **radial rigidity** to inhibit closure of the internal lumen(s). *In operation, the segments are configured so that they can provide **increased thermal resistivity** and/or **decrease the radially transmitted thermal conduction** and may also **provide increased structural rigidity**.*

(Paragraphs 0090-91) (emphasis added).

Each of these “features” teaches expressly away from Applicants’ specification, which seeks to improve the contact (and resulting conduction) of the active region of the catheter with the tissue being treated. There is simply no motivation to combine any of the teachings of Cioanta with Bednarek because the references are trying to solve entirely different problems. For at least this reason, the rejection under § 103 must be withdrawn.

The claimed inventions are patentable over the combination for an additional (and independent) reason, namely, combining the teachings of Cioanta with Bednarek will not produce Applicants’ invention. While Figures 3 and 4 of Cioanta present 27 different cross-sectional views, all of the cross-sections have the **same** cross-sectional **perimeter** – a circle. Indeed, Cioanta teaches increasing the structural rigidity so as to inhibit undue deformation. Thus, even if you did combine Cioanta with Bednarek, you would not have a cross-sectional configuration with “a flattened outer peripheral wall.”

Moreover, Cioanta teaches that you can configure the non-treatment portion of the catheter for various configurations. Thus, if you combine Cioanta with Bednarek, the result is a modification to the **non-treatment** portion of the catheter. The claimed invention is

directed to an improvement in the cross-sectional configuration along the active region of the catheter. Because the combination of Cioanta and Bednarek does not yield a treatment region having a cross-sectional configuration with a flattened outer peripheral wall, the combination cannot render obvious the rejected claims.

Applicants request that the rejection of claim 2 and 8 under § 103 be withdrawn, and thus, claim 1 (which is the same as the previous claim 2) and claim 8 are allowable over the prior art.

Dependent claims 5-7, 9, 11, 12, 14/12 and 15-18 are patentable for at least the same reasons that claims 1 and 8 are patentable. Accordingly, Applicants request that all of the pending claims be allowed.

Claims 7, 16, and 17

In connection with those claims that were directed to cross-sections having certain aspect ratios, the Examiner asserts that "it would have been obvious to construct the cross-section of the catheter according to the aspect ratio as claimed, since it has been held that discovering the optimum size only involves routine skill in the art." (Page 3 of the Office action). It is not clear what reference the Examiner is relying upon in making this statement. Cioanta does not address any D-shaped configurations, and so, for at least this additional reason, Applications submit that claims 7, 16 and 17 are patentable. If Examiner is relying on another reference, or upon personal knowledge, Applicants request clarification and further request that the Examiner direct Applicants to the specific passages upon which Examiner is relying.

Claims 3, 4, 10, 13, 14/13

Claims 3, 4, 10, 13, 14/13 were previous withdrawn in response to a restriction requirement. Upon allowance of Claims 1 and 8, Applicants request reconsideration of the previously withdrawn claims. These claims should be allowable for at least the reasons that claims 1 and 8 are allowable.

Newly Presented Claim 19

Applicants have added claim 19 drawn to a catheter having, among other things, an outer peripheral wall adapted to bias against the tissue in order to resist movement of the catheter relative to the tissue being treated. Support for this claim is found in Paragraph 0061 of Applicants' specification. Accordingly, it is believed that no new matter is introduced by this amendment, and it is submitted that this claim is patentable. Applicant believes that no additional fees are due by the addition of this single claim.

CONCLUSION

Applicants request prompt reconsideration of the pending rejections. Applicants submit that the application is in condition for allowance, and allowance of all pending claims is requested.

If there are any additional fees due with the filing of this document, including fees for the net addition of claims and/or any extension fees, the undersigned respectfully requests that any and all fees be charged to Deposit Account No. 50-1129. If any extension of time request or any petition is required for the entry of this paper or any of the accompanying papers, Applicants hereby petition or request the extension necessary. The undersigned authorizes any fee payment from Deposit Account No. 50-1129.

Respectfully submitted,

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